

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CEPHALON, INC.
41 Moores Road
Frazer, PA 19355

Plaintiff,

v.

HON. DAVID J. KAPPOS,
Under Secretary of Commerce for
Intellectual Property and Director of the
United States Patent and Trademark Office,
Office of General Counsel, United States
Patent and Trademark Office, P.O. Box
15667, Arlington, VA 22215
Madison Building East, Rm 10B20, 600
Dulany Street, Alexandria, VA 22314

Defendant.

Civil Action No. _____

Plaintiff Cephalon, Inc. ("Cephalon"), for its complaint against the Honorable David J. Kappos, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,566,805 ("the '805 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '805 patent be changed from 107 days to at least 149 days.

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

THE PARTIES

3. Plaintiff, Cephalon is a corporation, organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 41 Moores Road, Frazer, PA 19355.

4. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent & Trademark Office (“PTO”), acting in his official capacity. The Director is the head of the PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1361, 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

6. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

7. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

BACKGROUND

8. Plaintiff Cephalon is the assignee of all right, title and interest in the ‘805 patent, as evidenced by records on deposit with the PTO, and is the real party in interest in this case.

9. Magali Bourghol Hickey, Matthew Peterson, Orn Almarsson, and Mark Oliveira are the inventors of the patent application serial number 10/570,405 (“the ‘405 application”).

10. The ‘405 application was the National Stage of PCT/US2004/29013, filed on September 4, 2004, had a § 371 (c)(1), (2), (4) date of March 3, 2006, and issued as the ‘805 patent on July 28, 2009, indicating a patent term adjustment of 107 days. The ‘805 patent is attached hereto as Exhibit A.

11. 35 U.S.C. § 154(b) requires that patent terms be adjusted to compensate for failures of the PTO to take certain actions on patent applications within designated time limits. Specifically, 35 U.S.C. § 154(b)(3)(D) states that “[t]he Director shall proceed to grant the patent after completion of the Director’s determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.”

12. In calculating the patent term adjustment, the Director must take into account PTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the PTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

13. Under 35 U.S.C. § 154(b)(4)(A), “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action.”

CLAIM FOR RELIEF

14. The allegations of paragraphs 1-13 are incorporated in this claim for relief as if fully set forth herein.

15. The currently challenged patent term adjustment of the '805 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '805 patent, is 107 days. (*See* Exhibit A at 1). This determination of the 107-day patent term adjustment is in error. Pursuant to 35 U.S.C. § 154(b)(1)(B), the PTO failed to issue the '805 patent within 3 years of the actual filing date in the United States. Therefore, the correct patent term adjustment for the '805 patent is at least 149 days.

16. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is entitled to an adjustment of the term of the '805 patent of 256 days for PTO examination delay ("A Delay"). The A Delay consists of the following: (1) A period of 153 days pursuant to 35 U.S.C. § 154(b)(1)(A)(i) due to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the date on which the application fulfilled the requirements of 35 U.S.C. § 371; this period consists of the length of time from May 4, 2007 (14 months after the '405 application fulfilled the requirements of 35 U.S.C. § 371) to October 4, 2007 (the mailing date of the First Office Action); and (2) A period of 103 days pursuant to 35 U.S.C. § 154(b)(1)(A)(iv) due to the PTO's failure to issue a patent within 4 months after the date on which the issue fee was paid and all outstanding requirements satisfied; this period consists of the length of time from April 16, 2009 (4 months after the date the issue fee was paid) to July 28, 2009 (the date the '805 patent issued).

17. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an additional adjustment of the term of the '805 patent of 146 days due to the PTO's failure to issue a patent within 3 years after the actual filing date of the application in the United States ("B Delay"). The actual filing date in the United States of an international application is the date on which the national stage commenced under 35 U.S.C. § 371(b) or (f) (37 C.F.R. § 1.703(b)). The B Delay consists of the length of time from March 4, 2009 (3 years after the date on which the national stage commenced under 35 U.S.C. § 371(b)) to July 28, 2009 (the issue date of the '805 patent).

18. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent . . . periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." For the '805 patent, 103 days of the A Delay overlaps with the B Delay period; this period consists of the length of time from April 16, 2009 to July 28, 2009. Therefore, the 103 day period of overlap is excluded for the patent term adjustment.

19. Thus, the total period of PTO delay is 300 days, which is the sum of the period of A Delay (256 days) and the period of B Delay (146 days) minus the period of overlap (103 days).

20. Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of applicant delay, which is 149 days as determined by the Defendant.

21. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 149 days, which is the difference between the total period of PTO delay (299 days) and the period of applicant delay (150 days).

22. Moreover, Defendant's determination that the period of the patent term adjustment for the '805 patent is only 107 days is in conflict with this Court's decision in *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010), *aff'g Wyeth v. Dudas*, Civ. Action No. 1:07-cv-01492-JR, 2008 WL 4445642 (D.D.C. Sept. 30, 2008), which explains the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b).

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '805 patent from 107 days to 149 days, and requiring Defendant to alter the term of the '805 patent to reflect the 149 day patent term adjustment; and

B. Grant such other and further relief as the nature of the case may admit or require and may be just and equitable.

Respectfully submitted,

Dated: January 22, 2010

By: 

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